SIEMENS Healthineers

INNOVANCE® Heparin UF Control 1
INNOVANCE HEPARIN UF CONTROL 1
INNOVANCE® Heparin UF Control 2
INNOVANCE HEPARIN UF CONTROL 2
INNOVANCE® Heparin LMW Control 1
INNOVANCE HEPARIN LMW CONTROL 1
INNOVANCE® Heparin LMW Control 2
INNOVANCE HEPARIN LMW CONTROL 2

CE 0197

Revision bar indicates update to previous version.

Intended Use

For quality control of the INNOVANCE HEPARIN / INNOVANCE ANTI-XA assays for the quantitative determination of unfractionated heparin (UFH) and low molecular-weight heparin (LMWH) in citrated human plasma.

Remark: If not indicated otherwise, the term INNOVANCE HEPARIN Controls will be used within this Instructions For Use for all controls listed above.

Summary and Explanation

Heparin (UFH and LMWH) considerably accelerates the inactivation of thrombin and coagulation factor Xa (Xa) by antithrombin (AT). For this reason UFH and LMWH preparations are widely used as prophylactic and therapeutic anticoagulants. The main clinical indications for UFH are in prevention and treatment of venous thromboembolism, in certain types of coronary artery syndrome and in thrombotic stroke. LMWH has been replacing UFH in many of the latter's traditional indications. Due to numerous influences the anticoagulant effect of an identical dose of heparin varies from patient to patient[1,2].

Using the INNOVANCE HEPARIN / INNOVANCE ANTI-XA assays it is possible to quantify the activity of UFH and LMWH in a patient's plasma and to verify the intended target level.

The INNOVANCE HEPARIN Controls serve as quality controls for the INNOVANCE HEPARIN / INNOVANCE ANTI-XA assays.

Principles of the Procedure

The INNOVANCE HEPARIN Controls consist of plasmas containing defined activities of either UFH or LMWH. Recovery of these controls within their assigned ranges indicates proper functionality of the assay system.

Reagents

Note: INNOVANCE HEPARIN Controls can be used on automated coagulation analyzers. Siemens Healthineers provides Reference Guides (Application Sheets) for several coagulation analyzers. The Reference Guides (Application Sheets) contain analyzer/assay specific handling and performance information which may differ from that provided in these Instructions for Use. In this case, the information contained in the Reference Guides (Application Sheets) supersedes the information in these Instructions for Use. Please also consult the instruction manual of the instrument manufacturer!

Reagent	Description	Storage	Stability
INNOVANCE® Heparin UF Control 1 INNOVANCE HEPARIN UF CONTROL 1	Lyophilized reagent containing: • human plasma, citrated, containing UFH[a,b] • Stabilizer: • HEPES	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 24 hours[c]; 2–8 °C: reconstituted, 48 hours[c]; ≤ –18 °C: reconstituted, 4 weeks[c]
INNOVANCE® Heparin UF Control 2 INNOVANCE HEPARIN UF CONTROL 2	Lyophilized reagent containing: • human plasma, citrated, containing UFH[a,b] • Stabilizer: • HEPES	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 24 hours[c]; 2–8 °C: reconstituted, 48 hours[c]; ≤ –18 °C: reconstituted, 4 weeks[c]

Reagent	Description	Storage	Stability
INNOVANCE® Heparin LMW Control 1 INNOVANCE HEPARIN LMW CONTROL 1	Lyophilized reagent containing: • human plasma, citrated, containing LMWH[a,b] • Stabilizer: • HEPES	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 24 hours[c]; 2–8 °C: reconstituted, 48 hours[c]; ≤ –18 °C: reconstituted, 4 weeks[c]
INNOVANCE® Heparin LMW Control 2 INNOVANCE HEPARIN LMW CONTROL 2	Lyophilized reagent containing: • human plasma, citrated, containing LMWH[a,b] • Stabilizer: • HEPES	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 24 hours[c]; 2–8 °C: reconstituted, 48 hours[c]; ≤ –18 °C: reconstituted, 4 weeks[c]

[a] from pooled plasma collected from selected healthy blood donor
[b] For Heparin activities please refer to the lot-specific Table of Assigned Values.
[c] closed original vial

Reconstituted INNOVANCE HEPARIN Controls can be frozen and thawed once. The controls must be frozen as rapidly as possible in the original vial. Thawing must be accomplished at 37 °C within 10 minutes. The thawed control must be used within 2 hours when stored at 15 to 25 °C.

On-board stability
Information regarding on-board stability is specified in the Reference Guides (Application Sheets) for the different coagulation analyzers.

Warnings and Precautions

For *in-vitro* diagnostic use only.

For laboratory professional use.

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com/sds.

CAUTION! POTENTIAL BIOHAZARD
INNOVANCE HEPARIN UF CONTROL 1, INNOVANCE HEPARIN UF CONTROL 2, INNOVANCE HEPARIN LMW CONTROL 1, INNOVANCE HEPARIN LMW CONTROL 2
Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests that are CE marked or FDA approved for this purpose. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.

Caution
INNOVANCE HEPARIN UF CONTROL 1, INNOVANCE HEPARIN UF CONTROL 2, INNOVANCE HEPARIN LMW CONTROL 1, INNOVANCE HEPARIN LMW CONTROL 2
This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Not to be used for the determination of the activity or concentration of anticoagulants other than UFH and LMWH (e.g. heparinoids, synthetic pentasaccharides, direct factor Xa inhibitors). Danger of under- or overdosing resulting in thrombotic events or bleedings, respectively.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Summary of Safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public website: https://ec.europa.eu/tools/eudamed). In case Eudamed is not available, SSP can be delivered by Siemens Healthineers on request.

Preparing Reagents

Reconstitute INNOVANCE HEPARIN Controls with the labeled amount of distilled or deionized water. Mix carefully to dissolve (without foam formation).

Allow to stand at 15 to 25 °C for at least 15 minutes.

Mix gently once more before use.

Procedure

Materials Provided

REF	Contents		
OPOC03	INNOVANCE® Heparin UF Control 1 INNOVANCE HEPARIN UF CONTROL 1 Table of lot-specific Assigned Values	5 × →	1 mL
OPOD03	INNOVANCE® Heparin UF Control 2 INNOVANCE HEPARIN UF CONTROL 2 Table of lot-specific Assigned Values	5 × →	1 mL
OPOE03	INNOVANCE® Heparin LMW Control 1 INNOVANCE HEPARIN LMW CONTROL 1 Table of lot-specific Assigned Values	5 × →	1 mL
OPOF03	INNOVANCE® Heparin LMW Control 2 INNOVANCE HEPARIN LMW CONTROL 2 Table of lot-specific Assigned Values	5 × →	1 mL

Materials Required but not Provided

Item	Description
REF OPPU05	INNOVANCE ANTI-XA, INNOVANCE® Anti-Xa
REF OPOA03	INNOVANCE HEPARIN, INNOVANCE® Heparin
REF OPOB03	INNOVANCE HEPARIN CALIBRATOR, INNOVANCE® Heparin Calibrator
REF B4234-25	OV BUFFER, Dade® Owren's Veronal Buffer
REF OQUB19	Cleaner SCS (on BCS® XP System only)
Coagulation analyzers[d], such as:	• Atellica® COAG 360 System • BCS® XP System • SYSMEX CA-600 series • SYSMEX CS-2000i/CS-2100i System • SYSMEX CS-2500 System • SYSMEX CS-5100 System • SYSMEX CN-3000/CN-6000 System

[d] Availability of analyzers may vary by country.

Please note that the applications on other analyzers can be validated by the instrument manufacturer in accordance with the requirements of the REGULATION (EU) 2017/746 under their responsibility as long as the intended purpose and performance are not modified.

Refer also to the Reference Guide (Application Sheets).

Test Procedure

Pipetting of controls and reagents as well as mixing and processing is performed automatically by the analyzer. For details of this processing, refer to the Instruction Manual and Reference Guide (Application Sheet).

Results

Results are given in IU/mL.

Standardization

INNOVANCE HEPARIN Controls are traceable to the WHO (World Health Organization) International Standards for UFH and LMWH.

Technical Assistance

For customer support, contact your local technical support provider or distributor.
siemens-healthineers.com

References

1. Hirsh J, Raschke R. Heparin and low-molecular-weight heparin. The seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Chest. 2004;126:188S-203S.
2. Gray E, Mulloy B, Barrowcliffe T W, Heparin and low-molecular-weight heparin. Thromb Haemost. 2008; 99: 807-818.

Definition of Symbols

The following symbols may appear on the product labeling:

	Do not reuse		Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community	Σ	Contains sufficient for <n> tests
	Biological Risks	IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
NON STERILE	Non-sterile	CE	CE marking of conformity
CE 0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.	CONTENTS	Contents
	Reconstitution volume	LEVEL	Level
	Keep away from sunlight and heat	WARNING	Warning
DANGER	Danger	RxOnly	Prescription device (US only)
UDI	Device Identification (UDI) barcode	REACH xx/xx/xx	REACH Authorization Number

Legal Information

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